

BabyGel Pilot: the provision of alcohol handgel to postpartum mothers in Mbale, Eastern Uganda to prevent neonatal infective morbidity in the home.

Submission date 02/03/2015	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 18/03/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/04/2023	Condition category Infections and Infestations	☐ Individual participant data

Plain English summary of protocol

Background and study aims

There are an estimated 3 million neonatal deaths every year across the world. In Uganda, with over 1.5 million live births annually, 142,000 infants die every year before the age of five with 33% of these dying during the neonatal period (within the first 28 days of life). This places Uganda 153rd out of 163 countries in the global rank for frequency of neonatal deaths. Most newborn infections and deaths occur in the community, and are often not reported to the health sector. For example, preliminary findings from the Iganga/Mayuge Demographic Surveillance Site showed that 60% of all deaths occur outside a health facility setting and go unreported. Local community studies suggest an infection rate of around 30%. In terms of infection prevention, hand washing with soap even when washed with unclean water results in a large reduction in hand contamination. A recent systematic review concluded that there was a lack quality evidence for the effect of clean birth and postnatal newborn care practices on the number of neonatal deaths. However, the need for clean birth and postnatal care is widely accepted. A Delphi expert consensus process judged that clean birth practices at home with no skilled attendant could reduce neonatal sepsis deaths by 15% and tetanus deaths by 30%. The panel judged that improved postnatal newborn care practices could prevent 40% of neonatal sepsis deaths, but that more research is needed particularly on the content and quality of care during the early postnatal period. This research project seeks to determine whether the provision of alcohol hand gel to postnatal women in rural Uganda is a clinically and cost effective way of preventing early infant infections. The handgel comparison study is designed by WHO and the project questionnaires are published on the WHO website as part of the WHO 'Clean Care is Safer Care' campaign. The main research question is: does the addition of bitterants and perfume affect the acceptability of alcohol-based handgel? However, secondary research questions will be:

1. To determine the frequency of use of the product (and hence the volume used)
2. Does the addition of bitterants and perfume affect the tolerability of alcohol-based handgel?
3. Is the frequency of use related to its acceptability?
4. To determine the frequency of handrub use amongst postnatal women

5. To determine women's preference for size of handrub container, and whether this is related to frequency of travel out of their compound.

Who can participate?

Postnatal women with children aged under 3 months of age living in one of the villages participating in the study.

What does the study involve?

Participants are randomly allocated (according to which village they live) to receive one of 3 different alcohol handrubs in a predetermined order. Each participant uses the allocated handrub for 5 consecutive days followed by a 2-day 'washout' period in which they will not use any handrub. At the end of each week they are asked to return to the health centre to complete evaluation forms and to receive the next pack of handrub. Those who do not attend the follow-up are contacted by telephone and alternative way of follow-up with the research staff arranged (on an alternative day and / or an alternative, more convenient place).

The following alcohol handrub formulations are compared:

1. Plain alcohol handrub containing ethanol 80% (Alsoft V, Saraya East Africa Ltd).
2. Alsoft V with added bitterant: bitterant is normally added to prevent alcoholic abuse of the gel, but this may interfere with acceptability in women who normally eat meals with their hands
3. Alsoft V with an added floral perfume: The standard Saraya health care hand gel is unperfumed, but in the feasibility study women particularly liked a previous perfumed formulation that we used.

Participants are asked to use the handrub according to the WHO '4 moments for hand hygiene' in non-hospital settings. The data collection form is based on that produced by WHO and will be analysed using the WHO analysis tool.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Ten rural villages in Mbale district (Uganda)

When is the study starting and how long is it expected to run for?

March 2015 to February 2016

Who is funding the study?

Medical Research Council (UK)

Who is the main contact?

Professor Andrew Weeks

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

1.9

Study information

Scientific Title

BabyGel Pilot: a pilot study of a cluster randomised trial of the provision of alcohol handgel to postpartum mothers in Mbale, Eastern Uganda to prevent neonatal infective morbidity in the home.

Acronym

Babygel

Study objectives

To test the feasibility of conducting the main cluster randomised trial of the provision of alcohol handgel to postpartum mothers in prevention of neonatal infective morbidity in the community

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. University of Liverpool Ethics Committee
2. Mbale Regional Hospital Institutional Review Committee (MRHIRC)

Study design

An open, 2-arm cluster randomised trial with rural villages as the unit of randomisation in Eastern Uganda.

Primary study design

Observational

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Reduction in infant (>3 months) sepsis thereby leading to a possible reduction in infant morbidity and mortality

Interventions

A pilot study of a cluster randomised trial of the provision of alcohol handgel to postpartum mothers to prevent neonatal infective morbidity in the home.

This pilot study (work stream 1) will be used to formally pilot the planned main open, 2-arm cluster randomised controlled trial (RCT) comparing alcohol hand rub with normal care. This pilot is one of 3 studies being conducted in preparation for the main BabyGel cluster RCT, and will take place in 10 villages around Mbale, Uganda. Workstream 1 will assess the feasibility of conducting the main trial. Other workstreams are evaluating the optimal hand rub formulation (workstream 2) and consent procedures (workstream 3).

The study will be a 3-way, blinded, randomised cross-over study. Forty postnatal women with children aged under 3 months of age will be recruited through the infant vaccination clinics in two local health centres. The only exclusion will be of those who currently use antiseptic hand wash at home and wish to continue its use. The study will be explained to the women at the clinic and they will be given or read a participant information sheet, which will be translated into the local languages. Those who wish to participate will be asked to provide signed consent.

Participants will be randomly allocated to receive one of 3 different alcohol handrubs in a predetermined order. Each participant will use the allocated handrub for 5 consecutive days followed by a 2-day 'washout' period in which they will not use any handrub. At the end of each week they will be asked to return to the health centre to complete evaluation forms and to receive the next pack of handrub. Those who do not attend the follow-up will be contacted by telephone and alternative way of follow-up with the research staff arranged (on an alternative day and / or a alternative, more convenient place).

Intervention Type

Other

Primary outcome(s)

1. Infant sepsis (using the Young Infant Clinical Signs Study Group (YICSSG) criteria
2. Sepsis death in the first 90 days of life (assessed using verbal autopsy)

Key secondary outcome(s)

Neonatal: Physician diagnosed infant infection, Microbiologically confirmed infant infection rate in the first 90 days of life (blood culture and cerebrospinal fluid), Infant mortality at 24hrs, 7 days, 4 weeks, and 3 months of life, Individual infant infections, General: fever, clinical jaundice, Infant weight and height at 3 months

Maternal: Gel Hand hygiene compliance, frequency of other hand washing; Maternal postnatal pelvic infection, other infections and satisfaction.

Completion date

28/02/2016

Eligibility

Key inclusion criteria

1. Women with an estimated gestation of over 34 weeks
2. Reside in the participating villages.

The gestation age will be determined by the Last Normal Menstruation period (LNMP), and or Ultra sound scan.

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Women will be excluded from the study if they

1. Are temporary resident (visitors) in one of the Mbale villages
2. Plan to relocate to distant places (outside of the Mbale District) within 3 months of childbirth

Date of first enrolment

01/04/2015

Date of final enrolment

01/06/2015

Locations**Countries of recruitment**

Uganda

Uruguay

Study participating centre**Buwangolo Village**

Mbale District of Eastern Uganda

Mbale

Uganda

-

Study participating centre**Bulusambu Village**

Mbale District of Eastern Uganda

Mbale

Uruguay

-

Study participating centre

Namwaro

Mbale District of Eastern Uganda

Mbale

Uganda

-

Study participating centre

Namunyu

Mbale District of Eastern Uganda

Mbale

Uganda

-

Study participating centre

Bufukhula Central

Mbale District of Eastern Uganda

Mbale

Uganda

-

Study participating centre

Buwalasitoma

Mbale District of Eastern Uganda

Mbale

Uganda

-

Study participating centre

Makhonje Village

Mbale District of Eastern Uganda

Mbale

Uganda

-

Study participating centre

Namakye Village

Mbale District of Eastern Uganda

Mbale

Uganda

-

Study participating centre**Bunanimi Village**

Mbale District of Eastern Uganda

Mbale

Uganda

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Study participating centre**Bumulaa Toma Village**

Mbale District of Eastern Uganda

Mbale

Uganda

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Sponsor information

Organisation

University of Liverpool

ROR

<https://ror.org/04xs57h96>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/03/2019	25/04/2023	Yes	No
Other publications	Optimising informed consent for participants in a randomised controlled trial in rural Uganda: a comparative prospective cohort mixed-methods study	22/12/2018		Yes	No
Other publications	Preventing neonatal sepsis in rural Uganda: a cross-over study comparing the tolerance and acceptability of three alcohol-based hand rub formulations	20/11/2018	25/04/2023	Yes	No
Other publications	We have to clean ourselves to ensure that our children are healthy and beautiful: findings from a qualitative assessment of a hand hygiene poster in rural Uganda	03/01/2019	25/04/2023	Yes	No
Other unpublished results	In search of a primary outcome for community-based newborn infection trials in Eastern Uganda: a nested cohort study within the BabyGel pilot trial	13/03/2019	27/03/2019	No	No